Ms. Linda Vogt
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P. O. Box 176
Jefferson City, Missouri 65102-0176

Dear Ms. Vogt:

Re: Review Comments
Missouri's Risk-Based Corrective Action
Draft Final Technical Guidance

The U. S. Environmental Protection Agency (EPA), Region 7 has completed its review of the draft document "Departmental Missouri Risk-Based Corrective Action (MRBCA) Technical Guidance", dated February 2005. As a result of its review, the EPA has the following comments. This comment letter is a supplement to our preliminary review memo dated March 24, 2005.

GENERAL COMMENTS

As we understand it, this Guidance is intended to apply to all cleanups programs in the State of Missouri. However, the approach to establishing cleanup levels that is set forth in the Guidance is different in several important ways from the approach to establishing cleanup levels that is required by CERCLA. In some cases, cleanup levels established pursuant to the requirements of CERCLA will be more protective (i.e., "lower") than cleanup levels established using the MRBCA Guidance. For all cleanup sites being handled under CERCLA authority, the MRBCA Guidance can be considered as part of the evaluation and analysis of what are appropriate cleanup levels, but in the end, cleanup levels must be selected in accordance with the specific legal requirements of CERCLA.

In general, cleanup levels at CERCLA sites must meet two criteria: (a) cleanups must comply with all ARARs; and (2) cleanups must be protective of human health and the environment from a risk-based perspective. In determining what is protective from a risk-based perspective, lead agencies for CERCLA cleanups must follow the requirements of the National Contingency Plan (NCP), which is codified at 40 CFR Part 300. In practice, this means that for any given contaminant at a site, the lead Agency must do an analysis of what the appropriate risk based cleanup level is, in accordance

with the NCP, and also do an analysis of whether any ARAR exists for that contaminant. The ARAR-based cleanup level and the risk-based cleanup level are then compared, and the more stringent/more protective level is used.

The approach to establishing cleanup levels contained in the MRBCA Guidance differs from the CERCLA approach in two key ways: (1) it does not call for consideration of ARARs; and (2) it is not consistent with some aspects of the NCP. Because of these differences, the MRBCA Guidance cannot be used as the sole basis for determining cleanup levels at sites that are being handled under CERCLA authority. Following are more specifics on the provisions of the NCP that apply to establishment of cleanup levels.

1. When the agency conducts a Remedial Investigation (RI) and Feasibility Study (FS), the regulations require that a baseline risk assessment be completed. (40 CFR Part 300.430(d)(4)). As part of the RI/FS and Risk Assessment process the agency must evaluate actual and potential exposure pathways through environmental media (40 CFR Part 300.430(d)(2)(v)); actual and potential exposure routes, for example, inhalation and ingestion (40 CFR Part 300.430 (d)(2)(vi)); and other factors such as sensitive populations (40 CFR Part 300.430 (d)(2)(vii)).

2. The regulations provide that for systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety (40 CFR Part 300.430(e)(2)(i)(A)(*1*)). The factors as outlined here are the basis for the Agency using the reasonable maximum exposure scenario (RME) and for calculating risk based on a lifetime exposure scenario. The risk assessment and cleanup level selection process set forth in the MRBCA Guidance may conflict with these federal requirements.

3. For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10-4 and 10-6 using information on the relationship between dose and response. Perhaps most significantly, the regulations provide that the 10-6 risk level shall be used as the point of departure for determining remediation goals when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure (40 CFR Part 300.430(e)(2)(i)(A)(*2*)). The MRBCA guidance which uses 10-5 as point of departure may present a conflict with this section of our federal regulations.

4. With respect to ARARs, the NCP sets for an expectation that usable aquifers will be restored where practicable, and that maximum contaminant level goals (MCLGs) established under the Safe Drinking Water Act, that are set at levels above zero, shall be attained by remedial actions for ground or surface waters that

are current or potential sources of drinking water, where the MCLGs are relevant and appropriate based on factors in 300.400(g)(2). In addition, the NCP provides that water quality criteria established under sections 303 or 304 of the Clean Water Act shall be attained where relevant and appropriate. See 40 CFR Part 300.430(e)(5)(E). These provisions of the NCP could potentially conflict with the MRBCA should a cleanup level be developed that is less stringent than MCLs. MCLGs, or the water quality criteria established under the Clean Water Act.

RISK ASSESSMENT COMMENTS

Critical Comments

1. The MRBCA guidance makes no mention of the EPA's requirement for the evaluation of the reasonable maximum exposure (RME) scenario in risk assessment. The EPA guidance defines the RME as "the highest exposure that is reasonably expected to occur at a site. RMEs are estimated for individual pathways. If a population is exposed via more than one pathway, the combination of exposures across pathways also must represent an RME". The EPA's guidance goes on to say that "The intent of the RME is to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures" (EPA, 1989). Although current EPA policy is to present Central Tendency Estimates (CTE) in risk assessments in order to "give the risk manager additional information to consider while making decisions at a site", pursuant to the NCP "decisions at Superfund sites are based on cancer risks and non-cancer health hazards associated with RME estimates under both current and future land use conditions" (EPA, 2004a). ***We strongly advocate modifying the MRBCA guidance to retain this important information.***

2. The MRBCA guidance includes as part of the Tier 1 risk assessment a comparison of relevant risk-based target levels with "representative concentrations" of site contaminants of concern (COCs; see for example, Section 2.2.5). Appendix C of the guidance defines a representative concentration as "the average concentration to which the receptor is exposed over the specified exposure duration, within a specified geographical area, and for a specific route of exposure". For example, item five in Appendix C states "when calculating the representative groundwater concentration, first estimate the average concentration in each well based on recent data …. And then use the average of each well to estimate the representative concentration." The use of average contaminant concentrations in evaluating risk conflicts with EPA policy and guidance. In its comparison with target levels, the "representative concentration" discussed here is analogous to EPA's exposure point concentration. Rather than deriving an average exposure point concentration, EPA guidance states that "Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent upper confidence limit (UCL) of the arithmetic mean should be used for this variable (EPA, 1992)." For exposure areas with limited amounts of data or extreme variability in measured or modeled data, the maximum contaminant

concentration may be used in lieu of the 95% UCL (EPA, 1992). The EPA has made available the ProUCL software package to assist in the calculation of upper confidence limits for various data sets (EPA, 2004b). ***EPA strongly urges that the MRBCA guidance be revised to be consistent with EPA guidance through the use of a UCL of the arithmetic mean (or maximum contaminant level where limited data exists).***

3. Appendix E presents toxicity values for a number of chemicals, several of which are inconsistent with those used by EPA either because they appear to rely on older data (pre-Oct 2004 EPA Region 9 PRG update) or use other sources. ***Our preference is that the MRBCA guidance maintains consistency with EPA guidance regarding the hierarchy of acceptable sources for use in obtaining toxicity values (EPA, 2003) and is updated with current EPA toxicity values.***

4. The text of Section 7.2 gives several examples of data that may be eliminated from consideration, including "old data that is not considered representative of current conditions" and "data collected prior to any remediation at the site." Item 7 in Appendix C goes on to state that "in certain cases, data that [are] more than two years old may be used, but it must be justified." While EPA agrees that older data may often no longer be representative the ***EPA strongly recommends that where older data are to be excluded, the facility must provide sufficient justification as well as specific information regarding the data to be excluded.***

5. The MRBCA guidance contains contrary language in Section 8.7 concerning the calculation of site-wide risks. The bulleted items state that the cumulative site-wide carcinogenic risk must not exceed 10^{-4}, while the cumulative site-wide hazard index must not exceed 1.0. However, the next paragraph appears to indicate that Step 6 (i.e., the calculation of site-wide risks) "will apply only in cases where the number of COCs and routes of exposure may warrant the calculation of cumulative site-wide risk". The first full sentence on the next page goes on say that Step 6 would be needed only in "rare" instances. ***The EPA firmly believes that in order to adequately evaluate any potential concerns about additivity of risk across a site, the inclusion of a cumulative site-wide risk assessment must be calculated. The guidance should be modified to indicate that calculation of cumulative site-wide risk is the norm.***

6. Appendix E. All the equations which incorporate the dermal contact factor appear to have been taken from RAGS Part A. The dermal contact portions of RAGS Part A have been superseded by RAGS Part E (EPA, 2004c). ***All of these incorrect equations need to be revised to incorporate the most recent EPA guidance.***

7. The text in Section C.2.2.2 discusses the use of the Johnson and Ettinger model to estimate subsurface soil concentrations protective of indoor air inhalation. ***The EPA recommends that the text be modified to discuss the collection of indoor air samples in addition to use of the model.*** The EPA guidance recommends that

site-specific indoor air sampling be conducted as a complement to the use of the model, and to verify the accuracy of the model's site-specific predictive capability (EPA, 2002.). We have experience with several sites throughout the region where indoor air sampling documented contamination at levels of concern when the Johnson and Ettinger model indicated otherwise.

8. Section E.1 of the MRBCA guidance appears to omit the visitor and trespasser scenarios evaluated through the conduct of a traditional risk assessment consistent with RAGs. Although the risks associated with these scenarios typically are not used in establishing clean-up numbers, they are important to retain when evaluating risks using site-specific approaches since these scenarios may be the only ones that are uncontrollable, and might factor into the choice of corrective measures. ***The EPA recommends the MRBCA be modified to include both the visitor and trespasser scenario.***

9. Many of the exposure factors cited in Table E-3 are inconsistent with EPA guidance. Examples include factors for the soil ingestion rate for construction workers, inhalation rates for resident children and adults and non-residential workers, exposure times for indoor inhalation, indoor inhalation rates, outdoor inhalation rates, skin surface area, soil to skin adherence factors, and the target risk level. ***Since the source of the values presented in this table are not identified, EPA cannot evaluate the appropriateness of their use and therefore recommends modifying the MRBCA to include exposure factors consistent with EPA guidance.***

10. The groundwater to surface water exposure route is clearly a concern for contaminated sites with regard to ecological risk, but the potential for impacts to ecological receptors due to this exposure route is not clearly defined in Checklist A of Appendix F. ***The EPA recommends that the checklist should directly inquire as to whether there are potential surface water discharge points within any areas of groundwater contamination.***

11. Checklist B of Appendix F of the MRBCA guidance addresses complete ecological exposure pathways. Clearly, whether or not a species is an ecological receptor or an area is habitat for an ecological receptor is subjective. ***Therefore, a definition of an ecological receptor and ecological receptor habitat needs to be included in the guidance.*** The EPA defines an ecological receptor as any *ecological entity exposed to a stressor* (EPA, 1997). The following is a suggested definition for ecological receptor habitat, "*any area where an organism/ecological entity exists and is exposed to a contaminant or stressor*."

12. As part of the Level 2 Ecological Risk Assessment, site-specific COC concentrations are compared to risk-based eco-toxicity benchmarks. The list of sources for toxicity benchmarks that is provided in the Technical Guidance is incomplete and out-dated compared to those utilized by EPA. Additionally, EPA has substantial concern that the benchmarks will be misapplied if the comparisons

are done by individuals that are unfamiliar with how the toxicity benchmarks were derived, such as is the case in Table 5-1 which lists human health protection/fish consumption surface water values as ecological screening benchmarks. The Technical Guidance is also unclear as to which benchmarks from various sources should be used. For example, there are acute and chronic water quality criteria, many of which are dependent on the hardness or pH of the water. There are effects-range-low (ERL) and effects-range-medium (ERM) sediment quality criteria. ***The EPA strongly recommends that the MRBCA be modified to require that comparisons of COC concentrations to ecological benchmarks be done by trained biologists who are familiar with the ecological risk assessment process as well as with how various toxicity benchmarks are derived.***

General Comments

13. Appendix B of the MRBCA guidance contains values for roughly 350 contaminants. The EPA recommends consideration of expanding this list to include contaminants not identified in Appendix B, but for which values exist in EPA's Region 9 Preliminary Remediation Goal (PRG) tables.

14. The MRBCA guidance appears not to require the evaluation of contaminants for which MCLs exist (see for example, Sections E.2 and E.8). Unfortunately, MCLs are not always risk-based values due to the requirements of the Safe Drinking Water Act. Accordingly, EPA, Region 7 recommends that contaminants with MCLs still be evaluated in the risk assessment in the same manner as contaminants without MCLs.

15. Appendix E of the MRBCA guidance frequently uses terms (RAF_o, PC, RAF_d, M, VF_p, etc.) which are not used by EPA or found in EPA guidance and which appear to come from sources such as ASTM E1739-95, making assessment of the equations for consistency with EPA guidance very difficult. Since most risk assessors conducting risk assessment activities at corrective action sites are familiar with EPA's RAGS guidance this may prove confusing. Given the time frame established for review of the MRBCA guidance, EPA did not have the opportunity to review the supporting references and would recommend at minimum a cross-walk of terms and equations between the two documents.

16. For the purpose of clarity, Figure 2-2 should state that it is the maximum contaminant concentration that is evaluated for the exceedance of either DTLs or applicable WQS. Also, the figure should indicate that when DTLs or WQS are not exceeded, the party may petition the Department for a Letter of Completion, if that is indeed the case.

17. The text in Section 6.12 states that an adequate number of soil samples from each zone must be collected to meet the soil characterization objectives, stating that surface and subsurface soil "may include fill material – the distinction between

surface and subsurface soil is one of depth rather than composition." The EPA recommends that additional language be added to clarify that values obtained from sampling of clean fill as a result of corrective actions activities, would not be included as part of the risk assessment since these biased results would accordingly underestimate the degree of contamination present at the site.

18. The text in Section 6.15 states that sediment samples must be collected if data shows that contaminated groundwater is discharging to surface water. The EPA also recommends that if surface drainage pathways are suspected of having been impacted by any site contaminants, sediment (and surface water, if present) from those pathways should be sampled.

19. Section 8.6 discusses the use of analytical detection limits, and appears to limit that discussion to the use of EPA Method SW-846. The EPA recommends revising this section to include reference to other methods for contaminants of potential concern not included in the SW-846 suite of analytes.

20. The text of Section 8.7 refers several times to a "list of representative concentrations" contained in Tables 8-1(a) and (b); however no list appears to be contained in those tables.

21. The text of Section 11.2 requires that risk management plans include a mechanism for periodic examination and re-evaluation of new technologies. However, "periodic" is not defined. The EPA recommends that for consistency with the Superfund program an evaluation every five years may be appropriate. Additionally, the guidance may consider a different name for RMPs since this exact name already carries a connotation for many facilities as part of Clean Air Act requirements in case of chemical releases.

22. Item number 3 on page C-3 of Section C.1 discusses the need to "determine if the maximum concentration of any COC exceeds ten times the representative concentration of that COC for any exposure pathway." No further information appears regarding the next step if the COC exceeds ten times the representative concentration of that COC for any exposure pathway. If the guidance is to retain this, additional information should be provided (including the inappropriateness of applying this check with a limited data set).

23. Section E.1 of the MRBCA guidance considers surface soil to be represented by a depth of 0 – 3 feet. The EPA recommends that the MRBCA guidance follow existing EPA guidance which indicates "Assessment of surface exposures will be more certain if samples are collected from the shallowest depth that can be practically obtained…" (EPA, 1989). The EPA disagrees that a three-foot sample is representative of shallow surface conditions, especially for metals and other constituents that are less mobile.

24. Step 3 in Section E.8 in the establishment of target levels for groundwater protection identifies the use of point of detection (POD) wells. The text states that "POD wells are located between the source and the POE [point of exposure] to monitor the COC concentrations in groundwater as a means of protecting against exceedances at the POE. Risk-based target concentrations will be developed for the POD using appropriate fate and transport models and site-specific parameters as explained in Section E-12." However, no Section E-12 appears to exist.

25. The text in Section E.8 makes use of several dilution attenuation factor (DAF) values. Since these values are not consistent with EPA risk assessment guidance, the MRBCA document should explain the source of these values. This same comment applies to the default exposure factors in Table E-3 and the values presented in Table E-4.

TECHNICAL COMMENTS

26. In the past, the EPA and its contractors have supported MDNR in risk assessment review. The EPA will be unable to provide this level of support for risk assessments which utilize the MRBCA approach. The MRBCA process is sufficiently dissimilar from EPA's approach that it would require significant training of our risk assessors just to become familiar with the process. The EPA's concern is that with our limited risk assessment resources, we must focus our effort on maintaining staff's proficiency in changes, updates, and new information pertaining to the Superfund RAGS process.

27. The text in Section 6.5.3 requires a well survey to be conducted which locates all public water supply wells within a one-mile radius of the site, and all private water wells within a quarter-mile radius of the site. The EPA recommends that the radius of the private well survey be determined on a site-specific basis because some sites with groundwater contaminant plumes of greater aerial extent may warrant a survey with a larger radius.

28. Section 6.6, Analysis of Current and Future Groundwater Use: This section proposes to base characterization and clean-up decisions on an aquifer's demonstrated or potential usability. To streamline the process of making groundwater use determinations and to prevent ad hoc decisions and differing determinations between project managers, the state should consider establishing a state governmental workgroup to classify groundwater resources within the state. The EPA's guidance entitled *Final Comprehensive State Ground Water Protection Program Guidance* provides general recommendations for classifying groundwater resources. This document can be accessed at the following link: http://www.epa.gov/superfund/resources/remedy/pdf/100r-93001-s.pdf

29. Section 6.7 discusses soil characteristics of the vadose zone but does not account for secondary permeability. Please include the characteristic soil secondary permeability percent.

30. Section 6.7.1, Thickness of Vadose Zone and Depth to Groundwater, briefly mentions that depth to groundwater is used to determine vadose zone attenuation factors. It should also be noted here and elsewhere in this document where such factors are actually calculated that the validity of such calculations is dependent upon the existence of certain simplifying assumptions about the geology. First and foremost is the assumption that the vadose zone media in question is relatively homogenous and isotropic with respect to permeability. These common attenuation modeling assumptions are violated for most clays, however, due to the presence of significant fracturing (secondary porosity). The presence of significant fractures potentially provides a direct conduit for vapors to move with little attenuation between the water table and an overlying building. For this very reason, EPA's *User's Guide for Evaluating Subsurface Vapor Intrusion into Buildings* does not include clays within its table on soil types which may be used with the Johnson-Ettinger model (Table 11). This section of the MRBCA guidance should note that granular media-based attenuation factors should not be calculated for fractured media, including clay units, where direct pathways potentially exist between the water-table and overlying buildings.

31. Section 6.15, Distribution of Chemicals of Concern in Sediment and Surface Water Bodies: This section proposes to evaluate groundwater contaminant plume impacts on surface water bodies by collecting and analyzing surface water and sediment samples. However, this proposed approach may not be adequately protective of ecologic receptors within the receiving water body. Many organisms spend at least part of their time beneath the sediment-water interface in the hyporheic zone where they can be exposed to contaminant concentrations that are much higher than would be detectable within surface water alone. Sediment analyses that fail to include analysis of sediment pore water would also likely inadequately characterize impacts in this zone. Furthermore, great care must be taken in clearly locating actual discharge zones, since the location of such zones may not be intuitively obvious. If a surface water body is identified as a potential discharge point, a more detailed site-specific assessment of ecologic impacts should be required beyond simple surface water and sediment sampling. The EPA is in the process of developing a EcoUpdate/Issue Paper entitled *Evaluating Ground-Water / Surface-Water Transition Zones in Ecological Risk Assessments* which should be referenced as a general guide for completing such evaluations. This impending guidance is currently undergoing external peer review.

As these comments suggest, there are number of important issues that need to be discussed by the two agencies. The EPA will be represented at the Risk Based Remediation Rule Workgroup meeting in Jefferson City on April 28, 2005, at which stakeholder comments will be discussed; however, I suggest that we meet separately in

the near future to discuss these issues in greater detail. Please contact me at 913-551-7307 to arrange for a meeting.

Sincerely,

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cc: Leo Alderman, WWPD
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